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January 10, 2002

FILE: UTKO:002

CERTIFICATE OF MAJLING 37 C.F.R 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Parents, Washington, DC 20231, on the date below:

January 10, 200

Date

Mark T. Garrett

Commissioner for Patents Washington, DC 20231

RE:

SN 09/496,243 "WOVEN INTRAVASCULAR DEVICES AND METHODS FOR MAKING THE SAME AND APPARATUS FOR DELIVERY OF THE SAME" - Hyodoh et al.

#### Commissioner:

Enclosed for filing in the above-referenced patent application is:

- (1) A Fifth Supplemental Information Disclosure Statement, Form 1449, References C6-C9 (with copy of patent application U.S. Serial No. 60/118,211);
- (2) A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

No fees are believed to be due in connection with the filing of this Fifth Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10019609/MTG.

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Commissioner for Patents January 10, 2002 Page 2

Respectfully submitted,

Mark T. Garrett Reg. No. 44,699

MTG/jch
Encl.: As noted

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hideki Hyodoh et al.

Serial No.: 09/496,243

Filed: February 1, 2000

For: WOVEN INTRAVASCULAR DEVICES

AND METHODS FOR MAKING THE

SAME AND APPARATUS FOR DELIVERY OF THE SAME

Group Art Unit: 3731

Examiner: J. Woo

Attorney Docket. No.: UTKO:003/MTG

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Date

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Commissioner:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Fifth Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of

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record. Copies of the listed document required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Fifth Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

### Reference C6

Reference C6 includes seven photographs taken of stents ("the MK stents") displayed during a Japanese metallic stentgraft meeting ("the Japanese meeting") that occurred during the week of February 22, 1999. U.S. Patent Application Serial No. 60/118,211, to which the present application claims priority, was filed on February 1, 1999. (A copy of U.S. Patent Application Serial No. 60/118,211 is enclosed for the examiner's convenience.) The photographs were taken by Hideki Hyodoh at the Japanese meeting.

Dr. Hyodoh was told by a Dr. Matsui that the MK stents in the pictures were made by Dr. Matsui and by a Mr. Kitamura. Dr. Hyodoh was told by Dr. Matsui that: the MK stents were made using 0.35 mm diameter nitinol wire; the MK stents were made using only one nitinol wire per stent, the ends of which were soldered together near the mid-section of each stent; the MK stents were only used as aortic stentgrafts; a 16-18 French preloading sheath was used during the delivery of the MK stents; and the MK stents that were covered were covered with a polyester 0.12 mm sheet (collectively, "the MK stent information").

Dr. Matsui presented at the Japanese meeting the results of a clinical study involving the use of one or more of the MK stents in five or more patients to treat aortic arch aneurysms. Dr. Matsui also presented the results, and a description of the clinical study and MK stents used, via

an oral presentation accompanied by a slide show. Copies of the slides were not given to attendees of the Japanese meeting or to attendees of the slide show presentation. The results, including MK stents and a description of the clinical study, also were attached to a poster that could be viewed by attendees of the Japanese meeting. No written material in addition to the poster and slide show presentations concerning the MK stents was provided to any of the attendees of the Japanese meeting.

While in Japan, Dr. Hyodoh sent the photographs of the MK stents and the MK stent information to András Kónya in the United States of America on March 1 and 2, 1999.

# Additional Information Concerning the Japanese Meeting

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The stent depicted in Reference C8 ("the S stent") described below was presented by a Dr. Son via an oral presentation accompanied by a slide show at the Japanese metallic stentgraft meeting that occurred during the week of February 22, 1999 ("the Japanese meeting"). Hideki Hyodoh attended the oral and slide show presentation. The oral and slide show presentation concerned the results of a study using the S stent at least in the trachea of a patient. Copies of the slides were not given to attendees of the Japanese meeting or to attendees of the slide show presentation.

To the best of Dr. Hyodoh's knowledge and memory, the S stent was not presented via a poster at the Japanese meeting. Additionally, no written material in addition to the poster and slide show presentations concerning the S stent was provided to any attendees of the Japanese meeting. To the best of Dr. Hyodoh's knowledge and memory, the S-stent's construction is substantially similar, if not identical, to the construction of the MK stent discussed above: i.e., the S stent was formed from a single wire by hand and contained the two ends of the single wire were connected together, thereby eliminating any free wire ends.

### References C7

Reference C7 contains the cover page and two pages from Volume 10, Number 2, Part 2 of the February 1999 JVIR Supplement, which was mailed to its recipients on February 12, 1999.

### Reference C8

Reference C8 is a photograph taken by András Kónya of the S stent discussed above. The photograph was taken at the SCVIR meeting in Orlando, Florida that took place during the week of March 20-25, 1999 (the "1999 SCVIR meeting"). Drs. Kónya, Hyodoh, and Kenneth Wright attended the 1999 SCVIR meeting.

The S stent was presented via a poster that displayed one or more S stents and a description of an experiment involving use of multiple S stents (which experiment is described beneath the heading 'Poster No. 206 Iliac Arterial Stent Placement: Short-Term Results with a New Nitinol Stent' provided in Reference C7). Drs. Kónya, Hyodoh, and Wright each viewed that poster.

The S stent also was presented via an oral presentation accompanied by a slide show at the 1999 SCVIR meeting. The subject of the oral presentation and slide show was the same as the subject of the poster presentation of the S stent. Copies of the slides were not given to attendees of the 1999 SCVIR meeting or to attendees of the slide show presentation. No written material in addition to the poster and slide show presentations concerning the S stent was provided to any attendees of the 1999 SCVIR meeting.

### Reference C9 and Additional Information Concerning 1999 SCVIR Meeting

Drs. Kónya, Hyodoh, and Wright presented a description of an experiment they conducted (which experiment is described beneath the heading "Poster No. 198 A New Self-Expanding Bifurcated Stent: Preliminary Results" provided in Reference C7) via poster at the

1999 SCVIR meeting. Reference C9 is 3 copies of this poster. No written material in addition to this poster was provided to any attendees of the 1999 SCVIR meeting.

No fees are believed to be due in connection with the filing of this Fifth Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10019609/MTG.

Applicants respectfully request that the information included herein be made of record in the present case.

Respectfully submitted,

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January 10, 2002